510(k) Summary

MAY 3 1 2013

Submitter Information:

OsteoMed
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Contact Person: Piedad Peña

Date Prepared: February 18, 2013

Device Information:

Proprietary/Trade Name: ***OSTEOMED*** ExtremiFuse™ System
Common Name: Hammer Toe Implant

Classification Name:

- Regulation Number: 21 CFR 888.3040
- Regulation Name: Smooth or threaded metallic bone fixation fastener
- Product Code:
  - HWC

Device Class: II

Predicate Devices:

Pro-Toe VO HammerToe Implant System, K101165
Classification Name: Smooth or threaded metallic bone fixation fastener (**21CFR 888.3040, Product Code HWC**)
Device Class: II

OsteoMed Foot Plate and Screw Rigid Fixation System, K091614
Classification Name: Single/multiple component metallic bone fixation appliances and accessories (**21CFR 888.3030, Product Code HRS**)
Smooth or threaded metallic bone fixation fastener (**21CFR 888.3040, Product Code HWC**)
Device Class: II

OsteoMed Extended 2.0/2.4 Cannulated Screw System, K062863
Classification Name: Smooth or threaded metallic bone fixation fastener (**21CFR 888.3040, Product Code HWC**)
Device Class: II

Device Description:

The ***OSTEOMED*** ExtremiFuse System is indicated for small bone reconstruction limited to inter-digital repair and fusion of the phalanges. The ExtremiFuse implant is a one piece implant with a threaded portion and a barbed portion that holds the resected faces of the two phalanges together. The implant is offered in 3 diameter sizes of 2.4mm, 3.0mm and 4.0mm. For each size, the implant is available in angle configurations of 0° and 10°.

The system instruments include guide wires, broaches, cannulated drills, and implant drivers to facilitate the placement of the implants.

The ExtremiFuse implants are made from implant grade titanium alloy (Ti6Al4V) per ASTM F136. The instrumentation is made from various grades of surgical grade stainless steel, anodized aluminum, and/or medical grade plastic.

Intended Use:

The ***OSTEOMED*** ExtremiFuse System is indicated for the fixation of osteotomies and reconstruction of the lesser toes following correction procedures for hammertoe, claw toe, and mallet toe.

Technological Characteristics:

The ***OSTEOMED*** ExtremiFuse implant is recommended for arthrodesis of the proximal interphalangeal (PIP) joints of the Lesser Digits. The threaded portion of the implant is screwed into the proximal phalange to engage the bone and create a solid base. Following pilot drilling, the barbed side is pressed into the remaining distal phalange to create bone to bone contact during fixation.

ExtremiFuse devices are manufactured from titanium alloy (Ti6Al4V), the OSTEOMED Cannulated Screw System predicate. This material is biocompatible.

Performance / Clinical Data:

The ***OSTEOMED*** ExtremiFuse *System* was compared to the Pro-Toe VO Hammertoe Implant, the ***OSTEOMED*** Cannulated Screw System, and the ***OSTEOMED*** Foot Plating System, K-Wires. The ExtremiFuse implants underwent verification evaluation to ensure that the design features met the required mechanical strength criteria for their intended use. The intended use of the ***OSTEOMED*** ExtremiFuse implant is the same as the Pro-Toe VO Hammertoe Implant System predicate device (K101165).

Clinical Testing is not required to support substantial equivalence.

In conclusion, the device was evaluated to be safe and effective in performing as well or better when compared to the predicate devices for the intended use.

Substantial Equivalence:

A design and dimensional comparison was performed to establish substantial equivalence to the legally marketed predicate devices listed in this summary. The basis of substantial equivalence for this device is based on similarities in intended use, function, performance, design, technology and operational principles to the Pro-Toe VO Hammertoe Implant System (K101165), and similarities in material, function, and performance to the OsteoMed Cannulated Screw System (K062863) and OsteoMed Foot Plating System, K-Wires (K091614).

Substantial equivalence was shown through the pullout test, torque test, and bending test to the predicate devices. The indications, design, technology and operational principles are similar between the subject and predicate, Pro-Toe VO Hammertoe Implant, and therefore OsteoMed believes that the ***OSTEOMED*** ExtremiFuse *System* does not raise any new safety or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

OsteoMed
% Ms. Piedad Peña
Manager, Regulatory Affairs
3885 Arapaho Road
Addison, Texas 75001

Letter dated: May 31, 2013

Re: K130412
Trade/Device Name: Osteomed ExtremiFuse System
Regulation Number: 21 CFR 888.3040
Regulatory Class: Class II
Regulation Name: Smooth or threaded metallic bone fixation fastener
Product Code: HWC
Dated: March 18, 2013
Received: March 19, 2013

Dear Ms. Peña:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130412

Device Name: OsteoMed ExtremiFuse System

Indications for Use:

The ***OSTEOMED*** ExtremiFuse System is indicated for the fixation of osteotomies and reconstruction of the lesser toes following correction procedures for hammertoe, claw toe, and mallet toe.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices